



Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10774 & CMS-10008]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.
2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number: CMS-P-0015A

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10744	The International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS)
CMS-10008	Transitional Pass through payments related to Drugs, Biologicals, and Radiopharmaceuticals to determine eligibility under the Outpatient Prospective Payment System

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal

agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* New collection (Request for a new control number); *Title of Information Collection:* The International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS); *Use:* The HIPAA Act of 1996 required CMS to adopt standards for coding systems that are used for reporting health care transactions. The Transactions and Code Sets final rule (65 FR 50312) published in the Federal Register on August 17, 2000 adopted the International Classification of Diseases, 9th Revision, Clinical Modification (ICD–9–CM) Volumes 1 and 2 for diagnosis codes and ICD–9–CM Volume 3 for inpatient hospital services procedures as standard code sets for use by covered entities (health plans, health care clearinghouses, and those health care providers who transmit any health information in electronic form in connection with a transaction for which the Secretary has adopted a standard).

The ICD–10–PCS code set has been maintained, enhanced and expanded as a direct result of recommendations for updates (e.g. adding new codes, deleting codes, and editing descriptive material related to existing codes) received from interested stakeholders from both the public and private sectors. Thus, information collected in the application is significant to code set maintenance. The ICD–10–PCS code set maintenance is an ongoing process, as changes are implemented and updated; therefore, the process requires continual collection of information from applicants on a bi-annual basis. As new technology evolves and new complex medical procedures are developed, requests are submitted to CMS requesting modifications to the ICD–10–PCS code set. Requests have been received prior to HIPAA implementation and must continue to be collected to facilitate quality decision-making.

The Committee provides two meetings each year as a public forum to discuss proposed changes to ICD–10. Suggestions to CMS for ICD–10–PCS procedure code modifications come from both the public and private sectors. ICD–10–PCS modification requests can be proposals for new or revised procedure codes or requests for technical coding updates including but not limited to, enhancements to existing procedure code concepts, such as adding a new body part value or a new approach value. Requestors are asked to include a description of the procedure code or change being requested, and rationale for why the procedure code or change is needed. Supporting references and literature may also be submitted. Interested parties submit these ICD–10–PCS modification requests three months prior to a scheduled Spring or Fall C&M meeting via email to the following e-mail address: ICDProcedureCodeRequest@cms.hhs.gov. *Form Number*: CMS-10744 (OMB control number: 0938–New); *Frequency*: Yearly; *Affected Public*: Business or other for-profits and Not-for-profit institutions and Private Sector; *Number of Respondents*: 80; *Total Annual Responses*: 80; *Total Annual Hours*: 800. (For policy questions regarding this collection contact Marilu Hue at 410-786-4510.)

2. *Type of Information Collection Request*: Revision of a currently approved collection; *Title of Information Collection*: Transitional Pass through payments related to Drugs, Biologicals, and Radiopharmaceuticals to determine eligibility under the Outpatient Prospective Payment System; *Use*: Section 201(b) of the BBRA 1999 amended section 1833(t) of the Act by adding new section 1833(t)(6). This provision requires the Secretary to make additional payments to hospitals for a period of 2 to 3 years for certain drugs, radiopharmaceuticals, biological agents, medical devices and brachytherapy devices. Section 1833(t)(6)(A)(iv) establishes the criteria for determining the application of this provision to new items. Section 1833(t)(6)(C)(i) provides that the additional payment for drugs and biologicals be the amount by which the amount determined under section 1842(o) of the Act exceeds the portion of the otherwise applicable hospital outpatient department fee schedule amount that the Secretary determines to be associated with the drug or biological.

Interested parties such as hospitals, pharmaceutical companies, and physicians will apply for transitional pass-through payment for drugs, biologicals, and radiopharmaceuticals used with services covered under the hospital OPPS. After we receive all requested information, we will evaluate the information to determine if the criteria for making a transitional pass-through payment are met and if an interim healthcare common procedure coding system (HCPCS) code for a new drug, biological, or radiopharmaceutical is necessary. We will advise the applicant of our decision, and update the hospital OPPS during its next scheduled quarterly update to reflect any newly approved drug, biological, or radiopharmaceutical. We list below the information that we will require from all applicants. *Form Number:* CMS-10008 (OMB control number: 0938-0802); *Frequency:* Yearly; *Affected Public:* Private Sector; *Number of Respondents:* 30; *Total Annual Responses:* 30; *Total Annual Hours:* 480. (For policy questions regarding this collection contact Raymond A. Bulls at 410-786- 7267.)

Dated: May 5, 2021.

William N. Parham, III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P